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PATENT  
ATTORNEY DOCKET NO. 59866.000002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: )  
M. N. Holten-Andersen et al. )  
Serial No.: 09/546,573 ) Art Unit: 1642 ✓  
Filed: April 10, 2000 ) Examiner: S. L. Rawlings, Ph.D.  
)

For: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES  
TYPE-1 (TIMP-1) AS A CANCER MARKER

SUBSTANCE OF INTERVIEWS UNDER 37 C.F.R. § 1.133

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants wish to provide a summary of telephone interviews between Applicants' representatives and the Examiner.

I. December 31, 2003 Interview

The Examiner, Dr. Rawlings, called Stanislaus Aksman to advise that claim 1 would be in condition for allowance if references to predetermined sensitivity or predetermined specificity and discriminating value are deleted and if the claim recites that the individual is likely to have colorectal cancer if the total concentration of TIMP-1 is higher than the total concentration of TIMP-1 measured in a healthy control population and is unlikely to have colorectal cancer if the total concentration of TIMP-1 is lower than that in a healthy control population.

The remaining independent claims would have to be amended in a similar manner to place all claims in condition for allowance.

II. January 12, 2004 Interview

On January 12, 2004, an interview was conducted with the following participants:

- U.S. Patent and Trademark Office Personnel - Examiners Caputa, Eyler; and Rawlings;
- Applicants and their representatives: Dr. Nils Brünner, one of the named inventors, Peter Horn Møller, a patent consultant at Plougmann & Vingtoft, Copenhagen, Denmark, and Stanislaus Aksman, of Hunton & Williams in Washington, D.C.

The Examiners suggested that all claims would be allowable if references to discriminating value, specificity and sensitivity are deleted from independent claims, and operative steps of the method are inserted at least into dependent claims.

III. January 22, 2004 Interview

This interview was held between Stanislaus Aksman and Examiner Rawlings. Dr. Rawlings advised Applicants' representative that claim 1 would be in condition for allowance if it recited a series of steps, including:

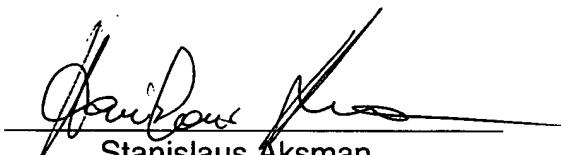
- a. determining a total concentration of TIMP-1 in a plasma sample of an individual;
- b. constructing a percentile plot of total TIMP-1 values from a non-colorectal cancer population and a ROC (receiver operating characteristics) curve based on the total plasma TIMP-1 concentrations in the non-colorectal cancer population and a colorectal cancer population;
- c. selecting a desired sensitivity and determining from the ROC curve the specificity corresponding to the desired sensitivity;
- d. determining from the percentile plot the total plasma TIMP-1 value corresponding to the specificity;

e. indicating the individual as likely to have colorectal cancer if the total concentration of TIMP-1 in the plasma sample of that individual is higher than the total plasma TIMP-1 value determined from the percentile plot and as unlikely to have colorectal cancer if the total TIMP-1 concentration in the plasma sample is lower than the total plasma TIMP-1 value determined from the percentile plot.

Any other independent claims would also have to be amended in a similar manner to place all claims in condition for allowance.

It is believed that no fees are due in connection with this response. However, if any fees are determined to be due, the Commissioner is hereby authorized to charge these fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,  
HUNTON & WILLIAMS LLP



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Stanislaus Aksman  
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Date: February 11, 2004

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